AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS

INVENTORS:

CHEUNG, et al.

APP NO.

N/A

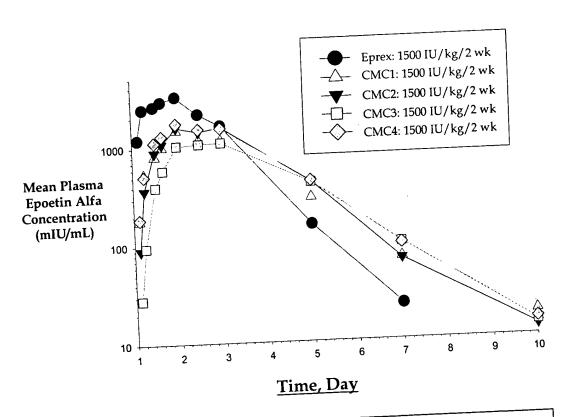
ATTY:

John W. Wallen, III

TELEPHONE: (858) 784-3239

ORT-1531 DOCKET NO.:

Figure 1



Dog Study:

Mean N =3 per group

 $15,\!000\,IU/g$ CMC1: 0.5% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH $15{,}000~\text{IU/g}$ CMC2: 1% CMC, 10~mM Na phosphate, 15~mg/g glycine, pH $15,\!000$ IU/g CMC3: 2% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH $15,000~{
m IU/g~CMC4}$: 2% CMC, $10~{
m mM~Na~phosphate}$, $50~{
m mg/g~manitol}$, pH

AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS TITLE:

CHEUNG, et al. **INVENTORS:**

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N/A

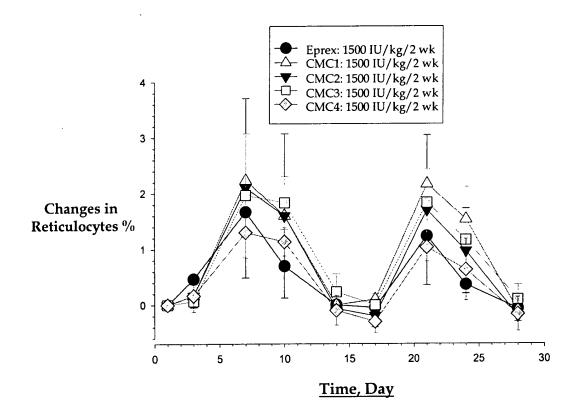
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Figure 2



Dog Study DM00032

Mean N = 3 per group

1/9/2001

15,000~IU/g~CMC1: 0.5%~CMC, 10~mM~Na~phosphate, 15~mg/g~glycine, pH~7 $15{,}000~IU/g$ CMC2: 1% CMC, 10~mM Na phosphate, 15~mg/g glycine, pH 715,000 IU/g CMC3: 2% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 7 15,000~IU/g~CMC4: 2% CMC, 10~mM~Na~phosphate, 50~mg/g~manitol, pH~7

AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS

INVENTORS:

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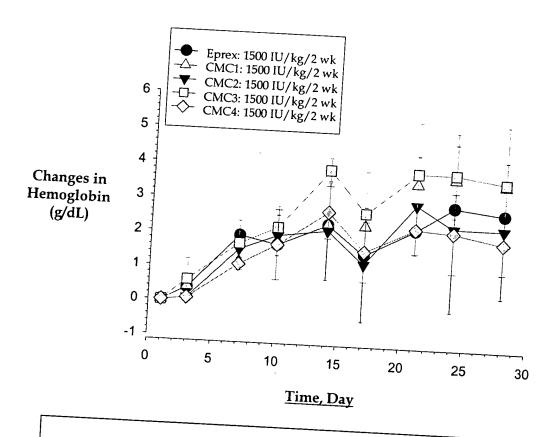
ATTY:

John W. Wallen, III

DOCKET NO.: ORT-1531 TELEPHONE:

(858) 784-3239

Figure 3



Dog Study

Mean N = 3 per group

15,000 IU/g CMC1: 0.5% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 7 $\,$ 15,000 IU/g CMC2: 1% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 7 $\,$ $15,\!000$ IU/g CMC3: 2% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 715,000 IU/g CMC4: 2% CMC, 10 mM Na phosphate, 50 mg/g manitol, pH 7

AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS

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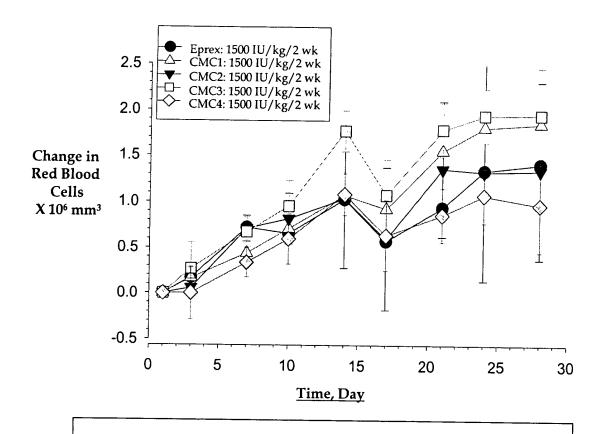
ATTY:

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Figure 4



Dog Study DM00032

Mean N = 3 per group

15,000 IU/g CMC1: 0.5% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 7 $\,$ 15,000 IU/g CMC2: 1% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 7 $\,$ 15,000 IU/g CMC3: 2% CMC, 10 mM Na phosphate, 15 mg/g glycine, pH 7 $\,$ 15,000 IU/g CMC4: 2% CMC, 10 mM Na phosphate, 50 mg/g manitol, pH 7 $\,$

TITLE: INVENTORS:

AQUEOUS SUSTAINED-RELEASE FORMULATIONS OF PROTEINS CHEUNG, et al. N/A

APP NO.

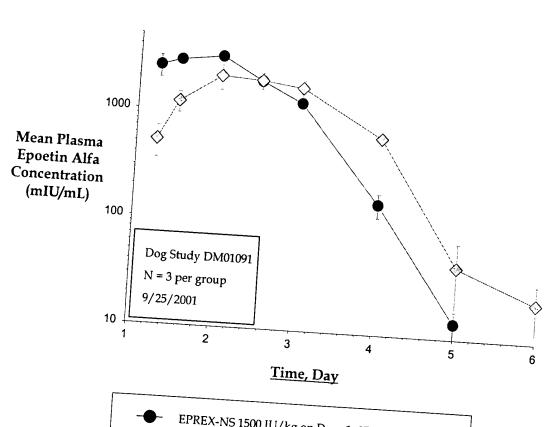
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Figure 5



EPREX-NS 1500 IU/kg on Days 1, 15, 29

Clinical Batch CMC-EPO 120,000 IU/mL, 2% CMC 125 mM NaCl, 1500 IU/kg on Days 1, 15, 29

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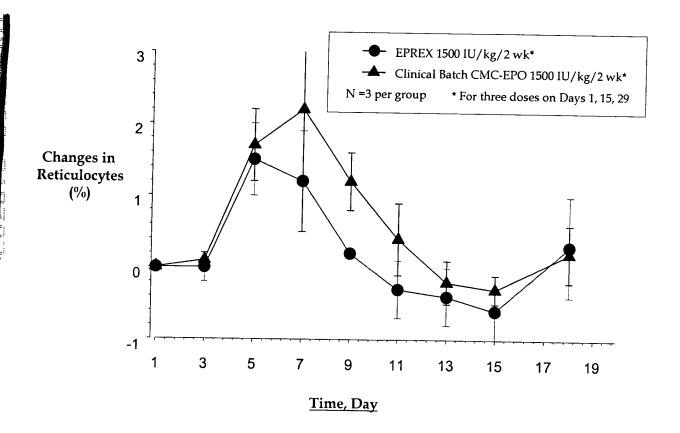
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Figure 6



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Figure 7

